FORM 10QSB

VASO ACTIVE PHARMACEUTICALS INC – VAPH

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Quarterly report filed by small businesses

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

FORWARD-LOOKING INFORMATION

This Quarterly Report on Form 10-QSB contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and section 21E of the Exchange Act of 1934, as amended, that are based on management's exercise of business judgment as well as assumptions made by, and information currently available to management. When used in this document, the words "may," "will," anticipate," believe," estimate," intend," and words of similar import, are intended to identify any forward-looking statements. You should not place undue reliance on these forward-looking statements. These statements reflect our current view of future events and are subject to certain risks and uncertainties as noted below. Should one or more of these risks and uncertainties materialize, or should underlying assumptions prove incorrect, our actual results could differ materially from those anticipated in these forward-looking statements. We undertake no obligation and do not intend to update, revise or otherwise publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of any unanticipated events after the date hereof or to reflect the occurrence of any unanticipated events. Although we believe that our expectations are based on reasonable assumptions, we can give no assurance that our expectations will materialize.

Management's Discussion and Analysis of Financial Condition and Results of Operations should be read together with our condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-QSB. This Quarterly Report on Form 10-QSB, including the following discussion, contains trend analysis and other forward-looking statements within the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Any statements in this Quarterly Report on Form 10-QSB that are not statements of historical facts are forward-looking statements. These forward looking statements made herein are based on our current expectations, involve a number of risks and uncertainties and should not be considered as guarantees of future performance.

The most predominant adverse factor affecting the future of the Company is its level of working capital. At March 31, 2005, we had working capital of approximately $750,000, which based on our current plans and assumptions relating to our operations, will be sufficient to satisfy our cash requirements through August 31, 2005. Our efforts to attract and obtain additional financing are significantly hampered by the shareholder and derivative actions involving our Company. See further discussion of this issue in the "CAPITAL AVAILABITY" and "LIQUIDITY AND CAPITAL RESOURCES" sections of the Management's Discussion and Analysis.

Additional factors that could cause actual results to differ materially include without limitation:

- interruptions or cancellation of existing contracts
- impact of competitive products and pricing
- product demand and market acceptance and risks
- the presence of competitors with greater financial resources
- product development and commercialization risks
- an inability to arrange additional debt or equity financing
- our ability to finance our business
- our ability to maintain our current pricing model and/or decrease our cost of sales
- continued availability of supplies or materials used in manufacturing at the current prices
- adverse regulatory developments in the United States
- entrance of competitive products in our markets
- the ability of management to execute plans and motivate personnel in the execution of those plans
- no adverse publicity related to our products or the company itself
- no adverse claims relating to our intellectual property
- the adoption of new, or changes in, accounting principles; legal proceedings
- the costs inherent with complying with new statutes and regulations applicable to public reporting companies, such as the Sarbanes-Oxley Act of 2002
- other new lines of business that the Company may enter in the future.

Actual results may differ materially from those set forth in such forward-looking statements as a result of factors set forth elsewhere in this Quarterly Report on Form 10-QSB, including under "Risk Factors." More information about factors that potentially could affect the Company's financial results is included in the Company's filings with the Securities and Exchange Commission.

OVERVIEW, KEY BUSINESS CHALLENGES AND RISKS

We are an early-stage company established for the purpose of commercializing, marketing and selling over-the-counter, or OTC, pharmaceutical products that incorporate topical and transdermal formulation platforms. We began our operations in January 2001, as a division of BioChemics, a biopharmaceutical company engaged in the development of transdermal and topical drug delivery systems. BioChemics is based in Danvers, Massachusetts. BioChemics was founded in 1989 by John J. Masiz and was incorporated in Delaware in 1991. BioChemics began developing the VALE technology in 1989 and has subsequently been issued 4 U.S. patents in connection with this technology. We are also based in Danvers, Massachusetts. In January 2003, we incorporated in Delaware and became an independent subsidiary of BioChemics, focused on the further commercialization of our existing OTC products and the development of new OTC product candidates.

As an early stage company, we are subject to a number of risks typical of early stage companies including, but not limited to, our need to obtain additional financing and generate profitability and cash flows from operations. As a company engaged in the pharmaceutical industry, we are subject to a number of risks typical of biopharmaceutical companies including, but not limited to, our need to adhere to strict governmental regulations, our ability to withstand intense competition from larger companies with greater financial resources and our ability to defend our intellectual property, as licensed from BioChemics.

Our general business strategy was adversely affected by regulatory and private securities actions taken against us and our management beginning in April 2004. At the same time, we suspended the marketing and sale of our products until we were reasonably sure that our product marketing was consistent with the FDA's requirements and policies. As a result of our voluntary delisting and continuation of delisting of our securities from the Nasdaq, the action taken by the SEC against us, the issues raised by the FDA regarding the regulatory status of our products, and the significant decline in the market value of our securities subsequent to these matters, several shareholder actions have been filed against the company and its officers and directors.

Many of our resources, including our cash and management time, have been diverted from our business strategy addressing these legal matters. We have incurred significant costs in defending ourselves and expect to incur additional costs to defend ourselves in the near future. We have primarily used the cash we raised in our December 2003 initial public offering to pay for these costs. In addition, we repaid approximately $7.5 million in cash in April 2004 that we raised in the private placement during March 2004. We intended to use the December 2003 offering proceeds to further our working capital and expand our business and marketing plans.

In August and September 2004, Vaso Active and its former Chief Executive Officer, John Masiz, settled all SEC and U.S. District Court matters regarding our alleged violations of securities laws stemming from allegedly misleading disclosures in our initial public offering registration statement, our 2003 annual report and a statement on our website concerning the FDA's approval or qualification of our products. Both Vaso Active and Mr. Masiz agreed with the SEC to settlement terms without admitting or denying the allegations of their civil complaint, pursuant to which both parties are permanently enjoined from violating the anti-fraud provisions of the 1933 Act, and the antifraud and reporting provisions of the 1934 Act. Our former Chief Executive Officer was also prohibited from serving as an officer or director of any public company, including Vaso Active, for a period of five years. He is, however, permitted to remain an active employee/consultant of Vaso Active. Since August 2004, Mr. Masiz has been employed by Vaso Active to provide consulting services pursuant to the terms of his employment agreement with the company. Also during 2004, together with newly engaged outside FDA counsel, we revised our product labels and in September began shipping our products on a limited basis. Although these products are now on the market, we have not made significant shipments or recorded significant revenues to date. You should refer to "Legal Proceedings," and "Risk Factors" for additional discussions surrounding these events.

The success of our marketing and sales activities will be dependent, among other things, on our ability to retain and attract qualified marketing and sales personnel, enter into qualified strategic partnerships, place our products into the market, the consumer perception of our products and the securing of additional financing. Although we believe that our products, supported by sufficient advertising, will earn retailers acceptance, there be no assurance that this will happen, or if it does, that it will continue.

Our independent auditors stated in their "Report of Independent Registered Public Accounting Firm" on our financial statements as of and for the years ended December 31, 2004, 2003 and 2002 that we may be unable to continue as a going concern. We anticipate that we have enough working capital to continue our current operations through August 2005. We will require additional financing to continue as a going concern. We are currently investigating financing options. We cannot provide any assurances that financing will be available to us, or even if we do obtain such financing, on favorable terms. We cannot provide any assurances that BioChemics will extend us additional financing or incur costs on our behalf.

TECHNOLOGY OVERVIEW

Transdermal drug delivery is generally considered to be any process of delivering drugs through the skin and into the bloodstream without the use of an invasive instrument such as a needle. We believe that transdermal drug delivery offers potential advantages over other commonly accepted modes of drug delivery for the treatment of certain diseases and medical conditions. We believe that these potential advantages include:

- REDUCTION OF ROUTE-OF-ADMINISTRATION RELATED SIDE EFFECTS. Because they are absorbed through the stomach, some orally administered medicines can cause significant gastrointestinal side effects, sometimes leading to discontinuation of the medication. There also may be side effects associated with the delivery of some drugs through the nasal lining, the lungs, and the skin using traditional methods. The goal of the VALE transdermal delivery system is to provide effective therapy while minimizing side effects.

- IMPROVED DRUG PERFORMANCE. Transdermal formulations may have the potential to improve the effectiveness of a drug by avoiding the stomach and the first-pass metabolism associated with oral delivery of drugs. Transdermal drug delivery also may have the potential to create a higher bioavailability index for certain drugs, allowing for the desired concentration of the drug molecule to reach the bloodstream from a smaller dose of drug applied to the patient. Bioavailability index is defined as the fraction of the drug amount administered that reaches the central circulation. By definition, bioavailability for a drug administered intravenously is 100% and drugs administered by other methods will typically have bioavailability indices of less than 100%, depending on the efficiency of drug transfer into the blood.

There are many different technologies used to deliver drugs transdermally. The most common technologies employed are: (i) patches that adhere to the skin, holding a drug in place while it is administered over time; (ii) liposome, or artificially prepared cell-like structures, which are applied topically and absorbed; or (iii) an outside energy source producing electricity (iontophoresis), or sound (sonophoresis), to help move the drug through the various skin layers. We believe all three of these technologies have certain drawbacks that may limit their utility.

We believe that Vaso Active's formulation technologies can be applied to a significant array of currently off-patent drugs for commercialization in the OTC marketplace. The VALE technology is a transdermal formulation that we believe may have the potential to introduce drugs through the skin and into the bloodstream in an efficient and effective manner. The PENtoCORE technology is a topical formulation that we believe allows for the formation of OTC products with certain "use advantages" over similar products marketed by our competitors. "Use advantages" include characteristics such as lack of odor, residue, and feel.

THE VALE TECHNOLOGY

The goal behind the development of the VALE technology is to create an active transdermal drug system that efficiently and effectively delivers drugs through the skin and into the blood supply without the need of a patch. In order to accomplish this, a delivery system must be able to overcome three skin barriers:

- the outer layers, or the stratum corneum and the epidermis;
- the second layer, or the dermis; and
- the walls of individual capillaries.

The VALE technology is intended to be a patchless, lipid-based delivery system which uses an active process to deliver drugs through the skin and into the bloodstream. It is being developed around the unique concept of incorporating chemical vasodilators into the drug delivery vehicle. These chemical compounds are intended to act on the network of blood vessels located near the surface of the skin to elicit the physiologic response of dilating or relaxing the blood vessels in the immediate area. This, in turn, is designed to have the effect of increasing the blood flow to the area. The theory behind the VALE technology is that as blood flow increases and the blood vessels dilate, the active drug molecules incorporated into the delivery system are transported actively and efficiently into the bloodstream.

We believe that the VALE technology has the potential to eliminate the need for a patch and to allow for the effective delivery of many active ingredients that may not otherwise be effectively delivered using existing drug delivery technologies.

THE PENTOCORE TECHNOLOGY

The PENtoCORE technology is a topical formulation, as opposed to the VALE transdermal technology. Although the PENtoCORE technology does not achieve its effect by delivering the drug through the skin and into the bloodstream, we believe that this technology may enable the formulation of topical products that are pleasant to use because they do not have the odor, greasy feel or residue often associated with other topically-applied drug products. In addition, it may be possible to use the PENtoCORE technology with certain active ingredients to develop topical formulations that facilitate a longer-lasting effect.

MANUFACTURING AND DEVELOPMENT AGREEMENT

In August 2003, we formalized a manufacturing and development agreement with BioChemics (the "Agreement") with respect to the ongoing manufacturing and development of our products and product candidates. The Agreement has an initial term of five years and shall be automatically renewed on each anniversary date of the agreement for an additional period of 12 months so long as the Agreement has not been terminated in acccordance with its terms and conditions. Under this agreement, BioChemics has and will continue to research, develop and manufacture products for us pursuant to specific purchase orders submitted by us from time to time. BioChemics will charge us a development and manufacturing fee at a rate of cost plus 10%. The Agreement permits BioChemics to use third party contractors to manufacture the products that BioChemics provides to us. Currently, BioChemics uses a privately owned third party company as its sole contract manufacturer. We do not currently, nor do we intend to, engage in the manufacturing of, nor conduct any research and development with respect to, any of our products or product candidates. However, in the event that BioChemics is unwilling or unable to meet our manufacturing needs in accordance with the terms of the Agreement with us, we have the right to retain outside third parties to manufacture our products. Pursuant to this Agreement, during the three-month periods ended March 31, 2005 and 2004, we incurred research and development costs of $90,030 and $95,167, respectively, related to the formulation of an analgesic utilizing the active ingredient ibuprofen. Pre-clinical studies utilizing animals were conducted and billed as part of this research.

ADMINISTRATIVE AND MANAGERIAL SUPPORT

Effective September 1, 2003, we entered into an administrative services Agreement with BioChemics. Under this agreement, BioChemics provides to us, at our request, administrative support services including secretarial support, accounting and tax services, data processing services, utilities, designated office space, designated warehouse and storage space, office supplies, telephone and computer services and equipment and such other office and corporate support services as we may reasonably require from time to time. BioChemics charges us an administrative services fee at a rate of cost plus 10%. This agreement is in effect for an initial term of 5 years and will be automatically renewable on each anniversary date for an additional period of 12 months unless sooner terminated (i) for a material breach by us, not cured within three months, and upon written notice (ii) upon 30 days written notice by us, (iii) upon 45 days written notice by either party if BioChemics ceases to own beneficially shares of our capital stock to which are attached at least 49% of the votes that may be cast to elect our Directors, or (iv) upon written notice by either party in the event that we shall have disposed of all or substantially all of our assets.

Pursuant to this agreement, since BioChemics provides us with administrative and managerial support, our results of operations include allocations of certain BioChemics expenses, such as centralized accounting, data processing, utilities, office space rental, supplies, telephone and other BioChemics corporate services and infrastructure. These expenses have been charged back to us as a management fee. The expense allocations have been determined on the basis that we and BioChemics consider to be reasonable reflections of the utilization of services provided for the benefit received by us.

GOVERNMENT REGULATION

General

The development, testing, manufacture, labeling, marketing, and promotion of OTC drugs are subject to extensive regulation by the FDA under the Federal Food, Drug and Cosmetics Act ("FFDCA"), and by the Federal Trade Commission, or FTC, under the Federal Trade Commission Act ("FTC Act").

The degree of regulation under the FFDCA is dependent, in part, upon whether the OTC drug, as formulated, labeled, and promoted, is considered by qualified experts, based on publicly available scientific data and information, to be generally recognized as safe and effective ("GRASE"), for its recommended conditions of use. If an OTC drug as formulated, labeled, and promoted is not considered GRASE for its recommended conditions of use or, if so considered, if it has not been used to a material extent or for material time, the drug is regulated under the FFDCA as a "new drug" which requires pre-market approval in the form of a New Drug Application, or NDA, before it can be commercially marketed.

To determine which OTC drugs are GRASE, the FDA has undertaken a rulemaking initiative in which it seeks to define by regulation which OTC drugs can be considered to be GRASE and thus can be marketed without first obtaining an approved NDA. This rulemaking initiative, referred to as the "OTC Review Program," was initiated on May 11, 1972, and is ongoing. The OTC Review Program sets forth in the form of an OTC Drug Monograph for specific categories of OTC drugs (e.g., Topical Anti-Fungal OTC drugs) the conditions under which recognized OTC active ingredients can be considered GRASE and not misbranded. These conditions include the strength of the active ingredient, acceptable dosage forms, the use of safe and suitable inactive ingredients, and the recommended conditions of use, including indications, warnings, precautions, and directions for use.

If the active ingredient used in an OTC drug is not covered by the OTC Review Program, or even if it is covered, if the conditions of use (e.g., strength, dosage form, indications) deviate from that eligible for GRASE status under the OTC Review Program, the product is considered by the FDA to be a "new drug" subject to the NDA pre-market approval requirements. For a full discussion of these requirements see the discussion below in "NDA Review Process".

Pending the issuance of a final and effective OTC Drug Monograph for the category of OTC drug involved (e.g., external analgesic), the FDA has adopted an enforcement policy of not proceeding against the continued marketing of OTC drugs subject to the OTC Review Program. This enforcement discretion does not, however, apply if: (a) the FDA considers the drug product involved as falling outside of the scope of the OTC Review Program in that the active ingredient or conditions of use deviate from those eligible for GRASE status under the OTC Review Program; (b) the product presents a health hazard; or (c)the active ingredient at the dosage level involved was not available OTC prior to December 4, 1975. The FDA's willingness to defer enforcement action generally terminates upon the effective date of the final OTC Drug Monograph covering the applicable drug product.

Other requirements or limitations for OTC drugs imposed under the FFDCA include: (a) a requirement that the drug be manufactured in conformity with current good manufacturing practices, or cGMPs; (b) a requirement that the labeling for the product contain adequate directions for use and warnings; (c) a requirement that the manufacturer of the drug product register with the FDA; (d)a requirement that all drugs manufactured for commercial distribution be listed with the FDA; and (e) a prohibition against making any false or misleading misrepresentations in any particular in any labeling for the product. As noted above, OTC products marketed in accordance with OTC Drug Monographs do not require FDA premarket approval prior to marketing. If an OTC product deviates from an OTC Drug Monograph requirement in active ingredient(s), intended use, method of administration, dosage form, or labeling, among other things, then the manufacturer or distributor must obtain pre-market approval in the form of an NDA before commercial marketing.

The failure to adhere to the requirements of the FFDCA can result in: (a) seizure of violative products; (b) injunctions against continued violations of the FFDCA, including active FDA supervision in instituting appropriate corrective action and prohibition against continued marketing of the violative products pending an affirmative determination by the FDA and the courts that the violations have been adequately rectified; (c) civil penalties in the form of liquidated damages and/or recovery of profits from illegal activities; and (d) the imposition of criminal sanctions and penalties against responsible persons.

The FTC, under the FTC Act, regulates print and broadcast media advertisements for OTC drugs. The FTC Act requires that advertisements be neither false nor misleading and that claims for products purportedly based on scientific data be supported by adequate and well controlled studies and that a reasonable basis exists in support of all other claims. Claims consistent with the terms of an OTC Drug Monograph are usually accepted by the FTC as having been adequately substantiated. The penalties for the failure of an advertised claim to have adequate substantiation, or for claims that are false and misleading, include: (a) the FTC initiating administrative action for consumer redress; (b) FTC seeking a court injunction to prevent further false and misleading advertising; (c) the imposition by a court of liquidated damages and equitable relief to recover profits and provide consumer redress from illegal activity; and (d) the placing of the company in receivership to assure that the assets of the company are not dissipated pending resolution of FTC claims.

THE NDA REVIEW PROCESS

The FDA has taken the position that insofar as our products or product candidates use a transdermal technology, the products fall outside that eligible for GRASE status under the OTC Review Program and thus the Company must obtain NDA approval of the products before they can be commercially marketed. Under the FDA's procedures it is generally less burdensome to obtain NDA approval of a drug product which contains active ingredient(s): (a) considered GRASE in a final OTC Drug Monograph, or (b) contained in a drug product eligible for an abbreviated new drug application, or ANDA, approval, but which differs in certain conditions of use (e.g., dosage form) from that covered by a final OTC Drug Monograph or eligible for ANDA approval. However, once a product becomes subject to the NDA requirements, the general provisions of which are set forth below, there can be no assurance that a company can generate the additional data and information necessary to support NDA approval of the proposed variant product or that approval can be obtained without substantial expenditures and delays.

The steps ordinarily required before a new drug that is subject to NDA approval may be marketed in the United States include preclinical laboratory tests, animal tests and formulation studies, the submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials on human subjects to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or the disease or condition for which the new drug is indicated. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon a manufacturer's activities. Success in early-stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit, or prevent regulatory approval. Even if a product receives regulatory approval, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

Preclinical tests include laboratory evaluation of product chemistry and formulation, as well as animal trials to assess the potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of compounds for testing must comply with Federal regulations and requirements. The results of preclinical testing are submitted to the FDA as part of an IND.

A 30-day waiting period after the filing of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not commented on or questioned the IND within this 30-day period, clinical trials may begin. If the FDA has comments or questions, the questions must be answered to the satisfaction of the FDA before initial clinical testing can begin. In addition, the FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. In some instances, the IND process can result in substantial delay and expense.

Clinical trials typically involve the administration of the investigational new drug to volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with Federal regulations and requirements, under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. subjects must be submitted to the FDA as part of the IND. The study protocol and informed consent information for patients in clinical trials must also be approved by the institutional review board at each institution where the trials will be conducted.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase I, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics and pharmacological actions and safety, including side effects associated with increasing doses. Phase II usually involves trials in limited patient populations, to determine dosage tolerance and optimum dosage, identify possible adverse effects and safety risks, and provide preliminary support for the efficacy of the drug in the indication being studied.

If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to further evaluate clinical efficacy and to further test for safety within an expanded patient population, typically at geographically dispersed clinical trial sites it is possible that Phase I, Phase II, or Phase III testing of product candidates may not be completed successfully within any specified time period, if at all.

After successful completion of the required clinical testing, generally an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of extensive clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of NDAs are additionally subject to substantial applications user fees, currently exceeding $500,000, and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees, currently exceeding $30,000 per product and $200,000 per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that the NDA is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under federal law, the FDA has agreed to certain performance goals in the review of NDAs. Most applications for non-priority drug products are reviewed within ten months. The review process is often significantly extended by FDA requests for additional information or clarification of information already provided in the submission. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee.

If FDA evaluations of the NDA and the manufacturing facilities and procedures, which typically involves an FDA on-site inspection, are favorable, the FDA may issue an approval letter, or, in some cases, an approvable letter followed by an approval letter. An approvable letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. If the FDA's evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or issue a not approvable letter. The not approvable letter outlines the deficiencies in the submission and often requires additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. With limited exceptions, FDA may withhold approval of an NDA regardless of prior advice it may have provided or commitments it may have made to the sponsor. As a condition of NDA approval, the FDA may require post-approval testing and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling restrictions. Such labeling restrictions can materially impact the potential market and profitability of the drug. Once granted, product approvals can still be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Once the NDA is approved, a product will be subject to certain post-approval requirements, including requirements for adverse event reporting and submission of periodic reports. Persons responsible for manufacture or distribution are subject to FDA inspections to assess compliance with applicable statutory and regulatory requirements.

Additionally, the FDA also strictly regulates the promotional claims that may be made about drug products. The FDA requires substantiation of any claims of superiority of one product over another including, in many cases, requirements that such claims be proven by adequate and well controlled head-to-head clinical trials. The FTC Substantiation Standards are very similar for the advertising of OTC products. To the extent that market acceptance of the Company's products may depend on their superiority over existing therapies, any restriction on the Company's ability to advertise or otherwise promote claims of superiority, or requirements to conduct additional expensive clinical trials to provide proof of such claims, could negatively affect the sales of our products and/or our costs.

CURRENT PRODUCT LINE

We have completed the development and test marketing of our three primary products. Each of these products uses the PENtoCORE technology. These products are:

- Osteon - an OTC external analgesic designed to provide temporary relief from the muscular-skeletal pain associated with arthritis;
- A-R Extreme - an OTC external analgesic designed to provide temporary relief from the muscle and joint pain associated with athletic activity (formerly branded as Athlete's Relief); and
- Termin8 - an OTC antifungal lotion designed to effectively treat athlete's foot (formerly branded under the name deFEET(R)).

We license the Osteon and PENtoCORE trademarks under our amended license agreement with BioChemics. We market each of our three current principal products under the OTC Review Program, witch is discussed in more detail under "Government Regulations".

PRODUCT CANDIDATES

In addition to and separate from our A-R Extreme, Osteon and Termin8 products, we have identified and are currently developing, in collaboration with BioChemics, six additional OTC product candidates that will utilize the VALE transdermal or PENtoCORE topical technology. Each of these product candidates are in various stages of development and are not yet available for sale. These product candidates are as follows:

- An analgesic utilizing ibuprofen;
- Toenail fungus treatment;
- Acne treatment;
- First aid treatments;
- Hand and body lotions; and
- Psoriasis treatment.

With regard to these product candidates, in instances where the active ingredient (e.g., ibuprofen), dosage form (e.g., VALE transdermal technology), strength, route of administration, directions for use or indication (e.g., toenail fungus) of the product candidate is not covered by the OTC Review Program or where the inactive ingredients used in the product candidate are not recognized as safe and suitable for their intended OTC use, we cannot market the product candidate without obtaining pre-market approval in the form of an approved new drug application, or NDA or an abbreviated new drug application, or ANDA. Conversely, where we believe the active ingredient, dosage form, strength, route of administration, directions for use, and indication of the product candidate are covered by the OTC Review Program and the inactive ingredients used in the product candidate are safe and suitable for their intended OTC use, the product candidate could be marketed without obtaining NDA or ANDA clearance, provided it conforms to the applicable OTC Monograph and is not otherwise adulterated or misbranded. You should refer to the information described under the caption "Government Regulation" for further discussion surrounding NDA, ANDA, OTC Review Program and OTC Monograph programs.

We have finalized a formulation of our acne treatment utilizing our PENtoCORE topical technology. We intend to market eventually the acne treatment under the label RepiDerm(R). The product would contain 10% benzoyl peroxide, or BPO, as an active ingredient. There is a final OTC monograph for acne drug products: however, the final monograph does not currently include BPO as an active ingredient.

In its tentative final Monograph for OTC acne drug products, the Food and Drug Administration, or FDA, proposed monograph status for BPO. However, following this proposal, the agency became aware of a study that raised a safety concern regarding BPO. FDA evaluated this study and other data submitted by a drug manufacturer association and, in 1991, the agency concluded that it was

unable to state that BPO is generally recognized as safe. Accordingly, the FDA published an amended tentative final monograph for OTC topical acne drug products in which it reclassified BPO from Category 1 (generally recognized as safe and effective and not misbranded) to Category III (available data are insufficient to classify as safe and effective, and further testing is required).

In light of the Category III status, the FDA subsequently concluded that the marketing under the OTC review program of BPO as an active ingredient in topical OTC acne drug products would be allowed to be continued (under the conditions set forth in the tentative final monograph, i.e. BPO at levels of 2.5 to 10%) while additional studies are conducted to answer the unresolved safety questions. However, the agency also tentatively determined that consumers who choose to use products containing BPO need to be provided additional information about the safe use of such products in the form of label warning statements regarding concomitant sunscreen use. There are numerous OTC acne treatment products containing 10% BPO that are currently being marketed under the OTC Review Program.

We believe that the active ingredients, dosage form, route of administration, directions for use, and indications of our RepiDerm acne treatment are covered by the OTC Review Program and, like similarly situated products on the market, can at this time be marketed under the OTC Review Program. We will begin marketing this product when we are confident that RepiDerm is covered by the OTC Review Program and its marketing is consistent with the FDA's policies regarding products that are being reviewed under the Program, specifically including BPO products. We expect to begin to market RepiDerm by the end of the third quarter of 2005.

COMPETITION

We are engaged in a rapidly evolving field. We compete primarily with established pharmaceutical companies like Pfizer, Bristol-Myers Squibb and Schering-Plough, emerging biotechnology companies like Alza, Cygnus and Elan, as well as research and academic institutions, among others. Competition is intense and expected to increase.

The large and rapidly growing market for transdermal and topical drug delivery systems is likely to attract new entrants. Numerous biotechnology and biopharmaceutical companies are focused on developing new drug delivery systems and most, if not all, of these companies have greater financial and other resources and development capabilities than we do. Our competitors also have greater collective experience in undertaking pre-clinical and clinical testing of products, obtaining regulatory approvals and manufacturing and marketing OTC and prescription pharmaceutical products. Accordingly, certain of these competitors may succeed in obtaining approval for products more rapidly than us. In addition to competing with universities and other research institutions in the development of products, technologies and processes, we may compete with other companies in acquiring rights to products or technologies from universities. There can be no assurance that our products or product candidates will be more effective or achieve greater market acceptance than competitive products, or that these companies will not succeed in developing products and technologies that are more effective than those being developed by us or that would render our products and technologies less competitive or obsolete.

Although we consider the PENtoCORE technology proprietary, the PENtoCORE products, which represent all our current products, do not enjoy any patent protection. This may allow our competitors to imitate or reverse engineer our current products and use their greater manufacturing and marketing resources to rapidly promulgate competing versions. It is our opinion that competing topical and transdermal delivery technologies using patches, liposomes, and equipment-assisted deliveries such as iontophoresis and sonophoresis have some utility with a small group of select drugs. It is our opinion, however, in general, that these drug delivery systems are not useful for most drugs. Our success will depend on our ability to leverage the PENtoCORE and VALE technologies to achieve market share at the expense of our existing and future competitors who we believe cannot offer products utilizing a delivery system of comparable performance characteristics.

In addition to competing with newly developed drug delivery systems, we will compete with existing products which address the same medical conditions as our products and product candidates. For instance, Tinactin(R) and Lotrimin(R) would compete with our Termin8 athlete's foot product, while Advil(R) and Tylenol(R) would compete with our pain relief products and product candidates. These and other brands are already offering different delivery systems. For instance, Pfizer's Ben Gay(R) is now offered in a patch as well as a cream. These products are manufactured, distributed and marketed by companies with vastly greater resources than our own. There is no guarantee we will be able to achieve widespread market acceptance for our products, or that our marketing efforts will be successful in distinguishing our products from these established market participants.

DISTRIBUTION

During 2004, we executed strategic alliances with Ortho Distribution Inc. or ODI and M2G Media.

In January 2005 ODI's parent company was purchased by an unrelated third-party. We are in ongoing discussions with the new ODI management and expect to continue the relationship. However, there can be no assurance that the strategic alliance will continue or that it will provide us with the results intended under the original agreement with ODI. We do not expect the new ODI management to pursue the alliance as strongly as prior management.

Regarding M2G Media, in late 2004, we were unable to reach mutually agreed upon product minimums with respect to the arthritis and pain relief markets and have since removed the arthritis and pain relief products from the M2G strategic alliance. We are currently negotiating with M2G Media with respect to launching our acne product, Repiderm.

Recent regulatory events and securities claims brought against us and our management has placed strains on our management and capital resources. In early 2004, we suspended the marketing and sale of our products until we were reasonably sure that our product marketing was consistent with the FDA's requirements and policies. In May 2004, together with outside FDA counsel, we revised our product labels and in September 2004 began shipping our products on a limited basis. Although these products are now on the market, we have not made significant shipments to date. You should refer to the discussions under the caption "Legal Proceedings" for further discussion on this matter.

We intend to pursue opportunities to launch our products into retail market chains sometime during late 2005. We believe that because retail sales efforts typically require large economic outlays and long sales cycles, they produce less of an immediate impact on operations than strategic alliances. Therefore, we have categorized this as part of the second phase of our rollout strategy. In January 2004, we engaged Commotion LLC, or Commotion, of Golden, Colorado, a strategic product marketing company, to assist us in establishing direct brand recognition and strategic retail rollout for our products. Since January 2004, Commotion has provided design input into our Company logos, stationary, business cards, product information and displays as well as for the revised labeling for our A-R Extreme, Osteon, Termin8, and RepiDerm products. Although the agreement is still in effect, we do not require additional design work at this time. Therefore in April 2005 we suspended our monthly retainer payment to Commotion until further notice.

Our plan is focused on the systematic rollout of our current products into major retail and drug store chains, select independent pharmacies and nontraditional channels, including multilevel marketing, direct marketing, web-sites and catalogues. However, as a result of the cessation of the marketing and sale of our products in early 2004 and changes in the timing for the retail rollout of our products, we do not anticipate using any of our initial public offering proceeds to fund our advertising, direct mail programs and related promotional activities. There can be no assurance that any of the initial public offering proceeds will be used for this purpose. You should refer to the discussions under the caption "Legal Proceedings" for further discussion on our cessation of marketing and sales activities.

OUTLOOK FOR 2005

During 2005, the Company plans to:

- Raise additional capital in order to continue the direct-to-consumer television campaign of its topical analgesic marketed under the label Osteon,
- expand retail distribution of its topical analgesic being marketed under the label AR-Extreme,
- begin retail distribution of its topical anti-fungal under the label Termin8, with its revised packaging,
- increase staffing, including outbound telemarketers and a senior marketing person with a background in retail launches, and
- introduce its new acne product under the label RepiDerm to the marketplace

Our strategy for Osteon is to create, through telemarketing, advertising and mailings a customer base of senior women and men suffering from osteoarthritis. We expect re-order sales of Osteon to carry higher gross profit margins than initial order sales of Osteon because re-order sales should not require the same direct media advertising expenditures as do the initial order sales. To achieve future growth, we plan to offer additional products, to be determined, that fit the demographic of this customer base.

Our strategy for AR-Extreme and Termin8 is to achieve market penetration through wholesale distribution to chain pharmacies, chiropractors, podiatrists, dermatologists, wellness and fitness centers. We are in the very early stages of this launch, which is constrained by our limited resources. We plan to allocate a portion of our planned future capital raise to hire additional personnel to accelerate this area of planned growth.

Our strategy for RepiDerm is to launch the product by the end of the third quarter of 2005. We plan to package and market this product under several labels. One label targeted to the teenage and young adult markets and another label targeted to older adults. This product is formulated to treat acne based upon regular usage and we expect to realize a re-order stream with any future customers. We are currently in negotiations with M2G Media to launch the product through either long or short form direct to consumer television media. Negotiations are ongoing and the details are not yet determined. If we are unable to reach a deal with M2G or with another strategic partner and if we are unable to raise additional capital, our planned launch of RepiDerm for the end of the third quarter of 2005 will be delayed.

CRITICAL ACCOUNTING ESTIMATES

GOING CONCERN ASSUMPTION - The financial statements do not include any adjustments relating to the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern. If the financial statements were prepared on a liquidation basis, the carrying value of our assets and liabilities would be adjusted to net realizable amounts. In addition, the classification of the assets and liabilities would be adjusted to reflect the liquidation basis of accounting.

REVENUE RECOGNITION - We recognize revenue from product sales in accordance with generally accepted accounting principles in the United States, including the guidance in Staff Accounting Bulletin, or SAB, No. 104, "Revenue Recognition," which supercedes SAB No. 101, "Revenue Recognition in Financial Statements," and Statement of Financial Accounting Standards, or SFAS, No. 48, "Revenue Recognition When Right of Return Exists."

Revenue from product sales is recognized when there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, and collectibility is reasonably assured. However, because our products are sold with limited rights of return, revenue is recognized when the price to the buyer is fixed, the buyer is obligated to pay us and the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from the us, we have no obligation to bring about the sale of the product and the amount of returns can be reasonably estimated.

We record allowances for product returns, rebates and discounts, and report revenue net of such allowances. We must make judgments and estimates in preparing the allowances that could require adjustments in the future. For instance, our customers have the right to return any product that is held past the labeled expiration date. We base our estimates on historic patterns of returns and on the expiration dates of product currently being shipped, or as a result of an actual event that may give rise to a significant return amount such as the discontinuance of a product.

We do not recognize revenue unless collectibility is reasonably assured. We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate and result in an impairment of their ability to make payments, additional allowances may be required.

EXPENSE ALLOCATIONS / MANAGEMENT FEES - BioChemics provides us with certain administrative, marketing and management services, as well as our facilities and general corporate infrastructure. Our statement of operations includes allocations of these costs that BioChemics that we considered to be reasonable. These costs are included in selling, general and administrative expenses.

INCOME TAXES - We account for income taxes and deferred tax assets and liabilities in accordance with SFAS No. 109 "Accounting for Income Taxes." Because we project future operating losses in the near term, we have provided a full valuation allowance against the deferred tax assets created by these losses.

STOCK-BASED COMPENSATION - As part of our compensation programs offered to our employees, we grant stock options. We grant stock options to employees based on the fair value of the Class A common stock at the grant date. As allowed under SFAS No. 123, "Accounting for Stock-Based Compensation," and SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure," we have adopted the disclosure-only requirements of these accounting standards. Accordingly, we do not recognize stock-based compensation expense for stock options granted to employees at their fair value. The fair value of options granted to non-employees are expensed in accordance with SFAS 123 using the Black-Scholes option-pricing model. See Note 4 to our condensed financial statements for the impact on earnings had we fully adopted SFAS 123.

In December 2004, the FASB issued a revision to SFAS No. 123, "Share-Based Payment," requiring companies to recognize as compensation expense the fair value of stock options and other equity-based compensation issued to employees. This revised statement eliminates the intrinsic value method provided under Accounting Principles Board, or APB, No. 25, "Accounting for Stock Issued to Employees," which is the method we currently use to value stock options awarded to our employees. This revised standard is effective as of the beginning of the first annual reporting period beginning after December 15, 2005 and is expected to have a material impact on our results of operations. We have not yet determined the impact that the revised statement will have on its financial condition and results of operations.

THREE MONTHS ENDED MARCH 31, 2005 AND MARCH 31, 2004

NET REVENUES - Net revenues for the three-month period ended March 31, 2005 decreased $2,550 to $4,597 from $7,147 in the comparable period in 2004. This period to period decrease was primarily a result of the regulatory and private securities actions taken against us beginning in April 2004 and our decision to suspend the marketing and sale of our products until we were reasonably sure that our product marketing was consistent with the FDA's requirements and policies. Since re-introducing our products to the marketplace in September 2004, with revised labeling, we have not generated significant revenues. No single customer represented more than 10% of net revenues in either period. All of our revenues during each of the periods were generated from the sale of our three OTC products.

COST OF SALES - In general, our cost of sales is variable to our net revenues. However, we maintain fixed manufacturing expenses. Also, certain manufacturing events such as inventory adjustments or product returns may significantly affect the consistency of our cost of sales, and therefore our gross profit, during any particular period. Cost of sales increased $473 to $6,248 from $5,775 in the comparable period in 2004. This increase in cost of sales was attributable to higher fixed manufacturing costs in 2005 versus 2004.

MARKETING, ADVERTISING AND PROMOTION - Marketing, advertising and promotion expenses increased $103,549, or 156%, to $169,803 for the three-month period ended March 31, 2005 from $66,254 in the comparable period in 2004. This increase was primarily attributable to $103,775 in costs we incurred in connection with our launch of a series of 60 and 120 second television commercials for the Osteon product throughout the United States. We will continue marketing Osteon in this manner in additional markets throughout the United States. We are seeking to buy additional television spots via a pay per unit sale deal, which links the amount we pay for television advertising to the actual amount of product purchased by consumers through these television spots. If we are unable to secure this pay per unit sale deal and instead must rely on fixed rate advertising alone, we will need to raise additional capital. We can provide no assurance that we will be able to secure a pay per unit sale deal or obtain additional capital.

SELLING, GENERAL AND ADMINISTRATIVE - Selling, general and administrative expenses decreased by $854,452 to $683,541 during the three months ended March 31, 2005 as compared to $1,537,993 in the comparable period in 2004. This decreased is due primarily to one-time charges we recorded in the three-month period ended March 31, 2004 of approximately $615,000 for fees paid to third parties in connection with our March 2004 private placement transaction (see Note 1 to our condensed financial statements) and $200,000 recorded as a general contingency which is the amount of the director and officers liability policy insurance deductible we could not expect to recover from the insurance carrier.

We continue to devote significant capital to defend ourselves against the civil complaints described more fully under the caption "Legal Proceedings" in this Quarterly Report on Form 10-QSB. During the three-month period ended March 31, 2005, we recorded approximately $57,700 in legal and professional fees to address these complaints.

RESEARCH AND DEVELOPMENT - Research and development expenses decreased $5,137, or 5%, to $90,030 from $95,167 in the comparable period in 2004. We continue to develop in collaboration with BioChemics an analgesic utilizing the active ingredient ibuprofen. Costs incurred related to this development have been consistent from period to period. Other research and development costs incurred relate to the formulation for our acne product, Repriderm.

STOCK-BASED COMPENSATION - We are required to record stock-based compensation when we grant options or warrants to purchase our common stock to non-employees in accordance with SFAS 123. The value of these options and warrants is calculated using the Black-Scholes valuation model. Stock based compensation for the three-month period ended March 31, 2004 included the award of a warrant to purchase 225,000 shares of common stock. As this warrant was completely vested, we recorded a charge of approximately $96,000 during the three month period ended March 31, 2004. The remainder of the stock-based compensation in both periods was attributable to the normal amortization of the fair value of these awards into expense over the vesting period of the awards.

CAPITAL AVAILABILITY

At March 31, 2005, we had working capital of approximately $750,000. We anticipate, based on our current plans and assumptions relating to our operations, that our current working capital will be sufficient to satisfy our cash requirements through August 31, 2005. We intend to continue as a going concern. However, unless we can obtain additional financing or generate profitability and cash flows from operations, we may not be able to continue as a going concern. Our efforts to attract and obtain such additional financing are significantly hampered by the shareholder and derivative actions involving our company. There can be no assurance that we will be able to obtain such additional financing or that, even if we do obtain additional financing, it will be on terms favorable to us. Further, there can be no assurance that we will be able to generate profitability and cash flows from operations with our existing working capital.

LIQUIDITY AND CAPITAL RESOURCES

The Company has incurred substantial operating losses and negative cash flows from operations since inception. In 2004, operations were financed from the proceeds of our December 2003 initial public offering. Net of offering costs, we raised approximately $6.4 million. Prior to our receipt of these proceeds, we relied on BioChemics as the source of our working capital.

At March 31, 2005, we had approximately $1.2 million in cash remaining from the initial public offering and working capital of approximately $750,000. Our financial condition has been materially and adversely affected by recent regulatory and shareholder actions taken against us. We expect to use portions of our working capital to continue defending ourselves in the balance of 2005. However, we cannot reasonably estimate the total costs to defend ourselves at this time. Further, we cannot provide any assurances that we will prevail in defending ourselves from the shareholder actions taken against us. In addition, our management intends to contest a substantial portion of the accounts payable shown on the Balance Sheet at March 31, 2005.

In March 2004, we entered into a private placement transaction with an institutional investor in the amount of $7,500,000. The investment was in the form of an 18 month 2% Convertible Note convertible into shares of Class A common stock at a conversion rate of $9.00 per share, at the option of the investor. Both principal and interest were payable in cash or in shares of Class A common stock at our option. Given that the initiation and continuation of the April 1, 2004 trading suspension by the SEC constituted a breach under the Note, we and the investor agreed, pursuant to the terms of a settlement agreement entered into on April 8, 2004, that we would immediately repay the investor the sum of $7,500,000 in cash without penalty, interest, redemption premium or any other premium or penalty, plus an expense reimbursement in connection with the settlement agreement in the amount of $15,000 in cash. In consideration of this repayment, the investor surrendered the Note and warrants and the parties mutually terminated all other agreements entered into in connection with the transaction. We intended to use these proceeds to further our working capital and expand our business and marketing plans.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The following table sets forth our contractual obligations and commitments for the next five years, as of March 31, 2005.

DESCRIPTION	2005	2006 - 2007	2008-2009	THEREAFTER	TOTAL
Long-term debt	$ --	$ --	$ --	$ --	$ --
Capital leases	--	--	--	--	--
Operating leases	--	--	--	--	--
Unconditional purchase obligations	--	--	--	--	--
Employment agreements	367,500	659,167	630,000	315,000	1,971,667
Total contractual obligations	$ 367,500	$ 659,167	$ 630,000	$ 315,000	$1,971,667

In February 2005, we appointed our Chief Financial Officer, Mr. Joseph Frattaroli, as our President. Mr. Frattaroli will continue to serve as Chief Financial Officer and Acting Chief Executive Officer. The terms and provisions of this appointment are being finalized in writing and will be disclosed when the agreement is completed in a form approved by the Board of Directors. This table is presented reflecting the authorized annual salary to Mr. Frattaroli effective March 1, 2005 for one year. The written employment agreements with Mr. Masiz and Dr. Carter terminate their initial terms on June 30, 2008, but are deemed automatically extended for successive periods of two years under the terms of their respective written agreements. This table is presented reflecting the effects of the deemed automatic extensions and it reflects $315,000 beyond 2009. This amount, $315,000, will be the annual ongoing obligation of the Company if the agreements for Mr. Masiz and Dr. Carter do in fact extend under the present agreements.

Mr. Masiz and Dr. Carter have agreed to waive, in writing, certain termination payout clauses contained in their respective employment agreements in the event that the Company becomes insolvent. Mr. Frattaroli has agreed in principle to a similar waiver, and will execute a similar waiver in writing when his employment agreement is finalized and executed.

OFF-BALANCE SHEET ARRANGEMENTS

We have no material off-balance sheet financing such as a facility lease or other long-term commitments. We have employment agreements with three key employees. Please refer to "Contractual Obligations and Commitments" for a summary of the employment agreement obligations.

OWNERSHIP STRUCTURE

Through our parent company, Biochemics, John J. Masiz controls approximately 70% of the combined voting power of all classes of stock of the Company and approximately 44% of the combined equity interest of the Company. Biochemics owns 100% of the Class B Common Stock of the Company.

RISK FACTORS

WE ARE AN EARLY STAGE COMPANY WITH A BRIEF HISTORY OF LOSSES AND MAY NEVER ACHIEVE OR SUSTAIN PROFITABILITY.

We do not have any continuing revenues and we have never been profitable and we may not achieve profitability in the foreseeable future, if at all. Our ability to generate profits in the future will depend on a number of factors, including:

- start-up costs relating to the commercialization, sale and marketing of our products;
- market acceptance of our products and product candidates;
- costs of acquiring and developing new product candidates;
- ability to bring our products to market;
- general and administrative costs relating to our operations;
- increases in our research and development costs;
- charges related to purchases of technology or other assets;
- ability to raise additional capital; and
- the favorable resolution of our current litigation (see "Legal Proceedings").

At March 31, 2005, we had an accumulated deficit of approximately $7.1 million. We expect to incur additional operating losses as we expand our marketing, sales and development efforts. If we are unable to generate sufficient revenue from our operations to pay expenses or we are unable to obtain additional financing on commercially reasonable terms, our business, financial condition and results of operations may be materially and adversely affected.

WE ARE AN EARLY STAGE COMPANY THAT HAS A LIMITED OPERATING HISTORY.

We are an early stage company focused on commercializing, marketing and selling OTC pharmaceutical products. We began our operations as a division of BioChemics, Inc. in January 2001. We have only operated as an entity independent of BioChemics since January 2003. Our operating history is therefore limited. Our Termin8, A-R Extreme and Osteon products, which we license from BioChemics, are in the early stages of commercialization. Our product candidates are only in the early stages of development. With the exception of the introduction of deFEET to the marketplace by BioChemics while we were still a division of BioChemics, we have not yet recognized significant revenue from product sales. You should evaluate the likelihood of financial and operational success in light of the uncertainties and complexities present in an early-stage company, many of which are beyond our control, including:

- our potential inability to market, distribute, and sell our products; and
- the significant investment of capital and other resources necessary to achieve our commercialization, marketing and sales objectives.

Our operations have been limited to organizing and staffing our company, acquiring our license, developing and testing our revenue distribution models and test marketing our products. These operations provide a limited basis for you to assess our ability to commercialize our products and product candidates and the advisability of investing in us.

THERE ARE SIGNIFICANT UNCERTAINTIES ABOUT OUR ABILITY TO CONTINUE AS A GOING CONCERN.

Our recurring operating losses, liquidity issues and the uncertainties raised as a result of our legal proceedings raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern and the appropriateness of using the going concern basis of accounting depends upon, among other things on, the ability to generate sufficient cash from operations and financing sources to meet obligations. At March 31, 2005, we had working capital of approximately $750,000. We anticipate, based on our current plans and assumptions relating to our operations, that our current working capital will be sufficient to satisfy our cash requirements through August 31, 2005. We intend to continue as a going concern. However, unless we can obtain additional financing or generate profitability and cash flows from operations, we may not be able to continue as a going concern. Our efforts to attract and obtain such additional financing are significantly hampered by the shareholder and derivative actions involving our company. There can be no assurance that we will be able to obtain such additional financing or that, even if we do obtain additional financing, it will be on terms favorable to us. Further, there can be no assurance that we will be able to generate profitability and cash flows from operations with our existing working capital.

OUR FAILURE TO COMPLY WITH EXTENSIVE GOVERNMENT REGULATION MAY SIGNIFICANTLY AFFECT OUR OPERATING RESULTS.

The worldwide marketing of our products and our product candidates are subject to extensive requirements by foreign, national, state and local governments. These regulations potentially impact many aspects of our operations, including testing, research and development, manufacturing, pre-market labeling, storage, quality control, adverse event reporting, record keeping, advertising and promotion. Failure to comply with applicable regulatory requirements could, among other things, result in:

- fines;
- changes to advertising;
- failure to obtain necessary marketing approvals;
- revocation or suspension of regulatory approvals of products;
- product seizures or recall;
- delay, interruption or suspension of product manufacturing, distribution, marketing and sale; or
- civil or criminal sanctions.

The discovery of previously unknown problems with our initial and future products may result in the interruption of marketing, including withdrawal from the market. In addition, the FDA may revisit and change any prior determination relating to the safety or efficacy of our products. If circumstances change, we may be required to change our labeling or cease the marketing and manufacturing of the product or products at issue. Even prior to any formal regulatory action, we could voluntarily decide to cease the distribution and sale or recall any of our future products if concerns about their safety or efficacy develop.

In their regulation of all our promotional materials, the FDA and the FTC may take issue with some advertising or promotional practices as being false, misleading or deceptive. The FDA or the FTC may impose a wide array of sanctions on companies for such advertising practices, which could result in any of the following:

- incurring substantial expenses, including fines, penalties, legal fees and costs to comply with FDA or FTC requirements;
- changing the methods of marketing and selling products;
- taking mandated corrective action, which may include placing advertisements or sending letters to physicians and marketing partners rescinding previous advertisements or promotions; or
- disrupting the distribution of products and causing the loss of sales until compliance with the FDA's or FTC's position is obtained.

If we become subject to any of the above requirements, it could be damaging to our reputation, and our business condition could be adversely affected.

WE CANNOT MARKET OUR PRODUCTS UNLESS THEY HAVE BEEN LISTED WITH THE FDA AND ARE COVERED BY THE FDA'S OTC REVIEW PROGRAM AND ARE MARKETED IN CONFORMITY WITH THE APPLICABLE OTC DRUG MONOGRAPH OR HAVE ATTAINED NDA OR ANDA APPROVAL.

If our topical A-R Extreme, Osteon and Termin8 products are formulated and promoted in accordance with the OTC Drug Monographs pursuant to the FDA's OTC Review Program, FDA pre-market approval is not required prior to marketing. If these or any of our product candidates deviate from an OTC Drug Monograph requirement in active ingredients, intended use, method of administration, dosage form, or labeling, among other things, then we or our marketing partners must obtain New Drug Application, or NDA, pre-market approval from the FDA before beginning commercial marketing. The FDA has taken the position that insofar as our product candidates may use the VALE transdermal technology, they fall outside of those eligible for generally recognized as safe and effective , or GRASE, status under the OTC Review Program and thus we must obtain, or our marketing partners must obtain, NDA approval of these product candidates before they can be commercially marketed.

Under the FDA's procedures, it is generally less burdensome to obtain NDA approval of a drug product which contains the same active ingredient(s) as those: (a) considered GRASE in a final OTC Drug Monograph, or (b) contained in a drug product eligible for abbreviated new drug application , or ANDA, approval, but which differs in certain conditions of use (e.g., dosage form) from that covered by a final OTC Drug Monograph or eligible for ANDA approval. However, once a product becomes subject to the NDA requirements there can be no assurance that a company can generate the additional data and information necessary to support NDA approval of the proposed variant product or that approval can be obtained without substantial expenditures and delays.

CLINICAL TRIALS MAY FAIL TO DEMONSTRATE THE SAFETY AND EFFICACY OF OUR PRODUCT CANDIDATES AND COULD PREVENT OR SIGNIFICANTLY DELAY REGULATORY APPROVAL.

Prior to receiving NDA approval to commercialize any of our product candidates, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other regulatory authorities in the United States and abroad, that the product candidate is both safe and effective. If these trials or future clinical trials are unsuccessful, our business and reputation would be harmed and our stock price would be adversely affected.

All of our product candidates are prone to the risks of failure. The results of early-stage clinical trials of our product candidates will not necessarily predict the results of later-stage clinical trials. Product candidates in later-stage clinical trials may fail to show desired safety and efficacy traits despite having progressed through initial clinical testing. Even if we believe the data collected from clinical trials of our product candidates are promising, these data may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory approval. Preclinical and clinical data can be interpreted in different ways. Accordingly, FDA officials could interpret such data in different ways than we do, which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities, or we may suspend or terminate clinical trials at any time. Any failure or significant delay in completing clinical trials for our product candidates, or in receiving regulatory approval for the sale of any products resulting from our product candidates, may severely harm our business and reputation.

Because of these risks, the research and development efforts of our collaborative partners may not result in any commercially viable products. If a significant portion of these development efforts is not successfully completed, required regulatory approvals are not obtained by our partners, or any approved products are not commercially successful, we are not likely to generate significant revenues or become profitable.

THERE IS NO ORGANIZED MARKET FOR OUR STOCK; OUR STOCK PRICE HAS BEEN VOLATILE AND COULD EXPERIENCE SUBSTANTIAL DECLINES.

Our securities are currently quoted in the Pink Sheets under the trading symbol "VAPH.PK". The market price of our common stock has experienced, and may continue to experience, significant volatility. Since the beginning of 2004, the per share closing price of our common stock has ranged from $0.38 to $14.11. As a result of the temporary suspension of trading in our securities on April 1, 2004, our press release dated April 7, 2004 advising investors not to trade in our securities until further disclosure, and our voluntary delisting of our securities from The Nasdaq Stock Market on April 8, 2004, there is not currently an organized market in our securities, and there can be no assurance that such a market will develop. On April 29, 2005 the average bid for a share of our Class A Common Stock as quoted by the OTC Pink Sheets was $0.65 per share. The value of our Class A Common Stock may decline regardless of our operating performance or prospects. Factors affecting our market price include:

- the success or failure of our product development efforts, especially those related to obtaining regulatory approvals;
- technological innovations developed by us or our competitors;
- variations in our operating results and the extent to which we achieve our key business targets;
- differences between our reported results and those expected by investors and securities analysts; and
- market reaction to any acquisitions or joint ventures announced by us or our competitors.

In addition, in recent years, the stock market in general, and the market for pharmaceutical companies in particular, have experienced significant price and volume fluctuations. This volatility has affected the market prices of securities issued by many companies, often for reasons unrelated to their operating performance, and it may adversely affect the price of our common stock. In the past, securities class action litigation has often been instituted following periods of volatility in the market price of a company's securities. A number of securities class action lawsuits have been filed against us. See "Legal Proceedings" for more information.

WE ARE DEFENDANTS IN A NUMBER OF CLASS ACTION LAWSUITS THAT MAY ADVERSELY AFFECT OUR BUSINESS.

As discussed in greater detail under "Legal Proceedings," we and certain of our officers are the defendants in a number of class action lawsuits filed on behalf of purchasers of Vaso Active's Class A common stock during the period December 11, 2003 to March 31, 2004, which allege that the defendants violated the federal securities laws by allegedly failing to make accurate and

complete disclosures concerning Vaso Active, its business operations and future prospects, the clinical trial and endorsement of our Termin8 anti-fungal product (previously known as "deFEET") and the institutional demand for Vaso Active securities. The complaints seek equitable and monetary relief, an unspecified amount of damages, with interest, attorney's fees and costs.

BioChemics, our directors and certain of our officers are also parties to three shareholder derivative actions alleging a breach of the defendants' fiduciary duties to the Company. The complaints seek equitable and monetary relief, an unspecified amount of damages, and attorneys and other fees, costs and expenses, ostensibly on behalf of the Company.

The securities class action lawsuits, and others which may be filed, could result in:

- potential liabilities;
- a material adverse financial statement impact
- substantial costs for defending these suits; and
- a diversion of management's attention and resources.

If there are adverse developments in the lawsuits against us, or resolution of our regulatory matters with the SEC and the FDA takes longer than we expect, our capital resources could be adversely affected. Should these actions linger for a long period of time, whether ultimately resolved in our favor or not, or further lawsuits be filed against us, our financial results will be adversely affected by the need to pay the fees and costs incurred in defending these suits. Additionally, we may not be able to conclude or settle such litigation on terms that coincide with our ability to pay any judgment or settlement. The size of payments for damages and other costs related to these actions, individually or in the aggregate, could seriously impair our cash reserves and financial condition. In addition, the continued defense of this lawsuit also could result in continued diversion of our management's time and attention away from business operations, which could cause our financial results to decline. A failure to resolve definitively current or future material litigation in which we are involved or in which we may become involved in the future, regardless of the merits of the respective cases, could also cast doubt as to our prospects in the eyes of our customers, potential customers and investors, which could cause our revenues and stock price to further decline.

OUR INSURER NOTIFIED US THAT IT REJECTS ITS LIABILITY TO REIMBURSE US WITH RESPECT TO ANY OF THE CLAIMS ASSERTED IN ANY OF THE CURRENT LEGAL PROCEEDINGS AGAINST US, OUR OFFICERS OR DIRECTORS. IF THE INSURER PREVAILS REGARDING THIS EVALUATION, IT MAY ADVERSELY AFFECT OUR BUSINESS.

We rely on our director and officer liability insurance policy to provide us with sufficient coverage to reimburse us for the cost of defense and, up to its coverage limit, to offset any unfavorable outcome which may result from class action lawsuits or derivative actions filed against us or our directors and officers. Our insurer has notified us that based on a coverage evaluation, it intends to reject liability to reimburse us with respect to any of the claims asserted in any of the litigation summarized under "Legal Proceedings" for a substantial majority of the policy coverage and that it may seek to rescind the policy with respect to the balance of the policy coverage. The Company intends to vigorously contest the insurer's positions. If the insurer prevails, it may adversely affect our capital resources and our business and, if the insurer prevails, we will bear responsibility for legal fees.

PROVISIONS IN OUR BYLAWS PROVIDE FOR INDEMNIFICATION OF OFFICERS AND DIRECTORS, WHICH COULD REQUIRE US TO DIRECT FUNDS AWAY FROM OUR BUSINESS OPERATIONS.

Our bylaws provide for the indemnification of our officers and directors. We may be required to advance costs incurred by an officer or director and to pay judgments, fines and expenses incurred by an officer or director, including reasonable attorneys' fees, as a result of actions or proceedings in which our officers and directors are involved by reason of being or having been an officer or director of the Company. Funds paid in satisfaction of judgments, fines and expenses may be funds we need for the operation of our business, commercialization of our current products and the development of our product candidates, thereby affecting our ability to attain profitability.